9/25/00

Commissioner Jane Henney
FDA Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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Re: Docket Number 00P-1211/CP1

Dear Commissioner Henney:

I am writing to voice my strong support for mandatory labeling and safety testing of genetically engineered (GE) foods and cosmetic ingredients, and to express my concerns.

Allergens

It is essential to provide identification of the source of any genes transferred from non-similar species. Requiring labeling only for transgenic foods containing "common" allergens is not enough. Food and cosmetic sensitivities are not limited to "common" allergens. Individuals who live with "uncommon" food and cosmetic sensitivities need to know if products contain compounds that they might be allergic to. Without explicit labeling, the lives and health of sensitive individuals are at risk.

The inclusion of genes from non-similar species makes an organism different from its non-GE counterpart. We will not be able to identify new allergens or other unanticipated problems in these products if they are not identified and labeled.

In addition, GE products should be segregated from non-GE products in the raw product distribution stream in order to provide an identification trail. This is done for organically produced products. It can also be done for genetically engineered products.

Health and Environmental Safety

I support a moratorium on all new genetically engineered plants and animals until it is conclusively demonstrated by long-term studies that they do not cause negative impacts on human or environmental health. As we are beginning to see, existing theories and studies are not adequate.

Transgenic foods and cosmetic ingredients should not be considered 'GRAS' without extensive testing to ensure their long-term safety for human health and the environment. Safety testing should be done by disinterested third parties, not by companies who have a financial incentive to bring their product to market.

Mandatory environmental testing is essential. Seeds and pollen cannot be contained in production fields. Seeds and pollen from GE plants can and do drift via movement by wind, animals, and farm equipment. Because of their very nature, biotech agricultural products cannot be reliably controlled, nor can their "behavior" be fully anticipated. The death of Monarch butterfly caterpillars as a result of exposure to pollen which drifted from Bt corn is a perfect example.

As you know, Bacillus thuringiensis (Bt) is a very important pest management tool in vector control and conventional agriculture, as well as organic agriculture. Bt crops will very likely result in insect resistance to Bt. This is a logical outcome of producing plants which contain continually expressed Bt toxin, and would be a serious loss of an effective insect control product.

Religious Considerations and Freedom of Choice

Religious freedom and freedom of choice are two of the foundations of our nation, and have always been issues of great importance to Americans. Two of the worlds major religions, and other smaller religions, observe dietary restrictions. Not labeling GE products violates the rights of followers of these religions to practice their faith by withholding important information regarding

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the inclusion of genes from forbidden sources. This violates an individual's right to religious freedom.

Lack of clear labeling denies the freedom of choice to individuals who choose to not use products from certain sources due to non-religious ethical considerations or other reasons. Lack of clear labeling denies me of my right to choose.

Genetically engineered crops were quietly mixed with conventional crops and were essentially "snuck" into the food supply without adequate notification or public input.

Public opinion polls consistently indicate that Americans want labeling of genetically engineered products. The majority of Americans are not even aware that foods they commonly consume contain genetically modified ingredients.

Substantial Equivalency

Genetic engineering is very different from conventional (non-transgenic) hybridization of plants and animals. Conventional hybridization does not cross genes across higher taxonomic levels, as is done in genetic engineering. Crossing genes between plants and animals is a new process; one which carries potential risks and consequences that cannot even be predicted, and for which natural controls might not exist. For this reason, genetically modified products should not be considered substantially equivalent to their non-GE counterparts.

Genetic Diversity

The future of our global food supply lies in maintaining genetic diversity in our food crops. Greater genetic diversity increases the ability of plant and animal species to adapt to environmental change. Genetic engineering endangers the future of our food supply by reducing diversity. Reducing diversity is a dangerous trend at a time when the world population is growing and climates are changing.

Please require clear and explicit labeling of genetically engineered foods and cosmetic ingredients. Full disclosure labeling which includes the source of any transferred genes is the only way to provide adequate information to consumers.

Genetically engineered plants and animals must be rigorously tested and the results subjected to peer review <u>before</u> they are allowed to be field tested. Genetic drift can cause serious damage which could be irreversible. This is a non-essential technology. The potential for environmental and health damage from the development and use of genetically engineered foods outweighs the potential benefits.

Food biotech should be required to follow safety procedures which are equally as stringent as those required for medical biotechnology. The industry has already experienced a number of problems including human deaths and disabilities caused by GE production of tryptophan; butterfly and beneficial insect deaths caused by pollen drift from Bt corn; and now the Taco Bell situation (which could have been avoided with adequate labeling and product separation).

Please add my name to your notification list for this issue.

Thank you.

Sincerely.

Stacy Brown

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